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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,249	11/17/2000	Susanne Dagmar Pippig	4-31192/CIP	7928

7590 10/22/2002

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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,249

Applicant(s)

PIPPIG ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-42 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 10, 11, 15-29, 33 and 36-39 is/are rejected.
- 7) ☒ Claim(s) 12-14, 31, 32, 34, 35, 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the amendment filed 9 August 2002 in which claims 1-6, 8, 10-14, 16, 17 and 20-29 were amended, claim 9 was cancelled and new claims 31-42 were presented.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 10-42 are pending.

Election/Restrictions

1. Claims 4 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
2. It is again noted that claims 1, 16, 20 and 27 are examined only to the extent that they read on the elected invention, a modified EGFR family member.

Drawings

3. Applicant's attention is drawn to the attached Draftperson's Review of the Drawings. Applicant is required to submit the proposed drawing corrections or corrected drawings within the time period set in this Office Action. See 37 CFR 1.85(a).

Claim Objections

4. Claims 1, 16, 20 and 27 are objected to because of the following informalities:
These independent claims still read on non-elected subject matter. Appropriate correction is required.

Specification

5. The disclosure is objected to because of the following informalities: The specification has two sequence listings. Applicant states that the listing labeled pp. 1-19 is identical to the submitted computer readable format. In view of this statement, Applicant is urged to delete pp. 41-50 to avoid any confusion regarding sequence compliance.

Appropriate correction is required.

Claim Objections

6. Applicant is advised that should claim 8 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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R s p o n s t o A m e n d m e n t

7. The rejection of claims 1-3 and 5-29 under 35 U.S.C. §112, first paragraph, for lack of an enabling disclosure has been withdrawn in view of Applicant's amendment.

 The rejection of claims 1-3, 6-15, 17 and 20-29 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

8. New grounds of rejection are presented below.

New Grounds of Rejection

9. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15 and 19 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

 Claims 15 and 19 recite the phrase "heterologous gene". "Gene" refers to an entire genomic structure encompassing all the regulatory regions (5' untranslated and 3' untranslated regions) as well as exons and introns. A representative number of eukaryotic genes for receptor binding polypeptides or chemokines is not known. Thus, the written description requirement has not been satisfied with respect to the word "gene".

This rejection would be overcome by amending the claims to recite "coding region".

Claim Rejections - 35 USC § 112

11. Claims 20-26, 28 and 36-38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite in being an independent claim which recites steps d) through f). This recitation suggests that there are steps a) through c) but it is unclear what these steps are.

Claim 28 is vague and indefinite in reciting "the nucleic acid encoding the mutated PTKR and the nucleic acid encoding the protein of interest" as this reads as though there are two different nucleic acids. However in parent claim 27 there is only one nucleic acid (line 3) introduced into the mammalian cell.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. §102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. §122(b). Therefore, this application is examined under 35 U.S.C. §102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. §102(e)).

13. Claims 1-3, 6, 7, 10, 11, 16-18 and 33 are rejected under 35 U.S.C. §102(b) as being anticipated by Vogelstein et al (WO 91/03489 A1). Vogelstein et al teach introducing an expression vector expressing a mutated epidermal growth factor receptor (EGFR) into a mammalian cell, expressing the mutated EGFR and identifying and separating out those cells expressing the construct, in order to purify the expressed EGFR. The mutation in the EGFR is selected from: a deletion in the extracytoplasmic domain or essentially a truncation of the entire extracytoplasmic domain; both of these are modifications to the extracellular domain. The expression vector may be a retroviral vector. Introducing the expression vector into human cells is taught. Based on the teaching on p. 1, last paragraph, it is assumed that the EGFR disclosed is EGFR1. See entire document, especially pp. 10-15 and Figures 1-3.

14. Claims 1-3, 5, 6, 8, 10, 15-17, 19, 20, 22, 27-29, 33, 36 and 39 are rejected under 35 U.S.C. §102(b) as being anticipated by Kashles et al (Mol Cell Biol (1991) 11:1454-1463). Kashles et al teach transfecting 3T3 cells with expression vectors encoding mutated EGFR coding sequences wherein the mutation is in the intracellular domain of EGFR. The vectors further comprise a heterologous coding sequence which provides geneticin (G418) resistance. In some cases, cells were also transfected with a

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coding sequence for wild-type EGFR, which could also be considered the protein of interest. Cells are immunoprecipitated with ¹²⁵I-labeled monoclonal anti-EGFR antibody to identify and separate cells expressing EGFR. See entire document, especially Abstract, Figure 1 and the first paragraph under "Results" on p. 1457.

15. Claims 1-3, 5-8, 10, 11, 15-20, 22, 23, 27-29, 33, 36 and 39 are rejected under 35 U.S.C. §102(e) as being anticipated by Chen et al (USP 6,235,729 B1). Chen et al teach transducing human prostate cancer cells with an expression vector which comprises a coding sequence for a mutated EGFR, c'973, and a coding sequence of a neomycin phosphotransferase gene (a protein of interest). The mutated EGFR, c'973, has an intracellular domain mutation such that it is truncated after amino acid 973. The transducing vector was a murine moloney leukemia virus-based retroviral vector. Cells comprising the vector were selected using G418-resistance and cells were treated with, for instance, ¹²⁵I-labeled antibody to identify those cells that express the mutated EGFR. See entire document, especially col. 3, lines 6-10 and Examples 1-3, 10 and 21. It is assumed that the EGFR used was EGFR1 based on the teaching in col. 8, lines 63-64.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

18. Claims 1-3, 6-8, 10, 11, 16-18, 20, 22, 25, 26, 33 and 37 are rejected under 35 U.S.C. §103(a) as being unpatentable over Vogelstein et al. Vogelstein et al is applied to claims 1-3, 6, 7, 10, 11, 16-18 and 33 as above. Vogelstein et al do not explicitly teach using a labeled antibody to identify transfected cells expressing the mutated EGFR.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to use such antibodies to identify those transfected cells that are expressing the mutated EGFR. One of ordinary skill in the art would have been motivated to do because Vogelstein et al teach the use of labeled antibodies which specifically recognize the mutated EGFR is taught. Using such antibodies to detect the mutated EGFR in tissues is also taught and one of ordinary skill in the art would therefore reasonably expect success in using the antibodies to identify desired transfected cells. See for instance pp. 18-19 and pp. 42-43.

Conclusion

Claim 42 is allowed. Claims 1-3, 5-8, 10, 11, 15-29, 33 and 36-39 are rejected. Claims 12-14, 31, 32, 34, 35, 40 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Customer service for Tech Center 1600 may be reached at (703)-308-0198.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

October 18, 2002


JAMES KETTER
PRIMARY EXAMINER